

REMARKS

In reply to the Office Action dated September 24, 2004, claims 4, 8-10, 19, and 62-64 are currently pending, with claims 4, 8-10, 19, and 62-63 under examination. By the above amendment, claims 19 and 64 have been canceled and claims 4, 8 and 10 have been amended, support for which can be found throughout the specification as originally filed. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Applicants note that the Brief Description of the Drawings section has been amended, as requested, to include identifiers for the sequences set forth in Figures 8, 9 and 11.

Applicants further note that the Examiner has granted priority for the claimed subject matter to Application 09/232,149, filed January 15, 1999. A Supplemental ADS is enclosed herewith to reflect this priority information.

A corrected substitute specification, and clean copy of the substitute specification containing page numbers, are also enclosed herewith as requested. In addition, amendments to the specification are set forth above updating the statement of priority, capitalizing the trademark GENBANK™, and adding a description for Figure 11 to the Brief Description of the Drawings.

Sequence Compliance

The Examiner notes that the specification fails to comply with the sequence disclosure requirements set forth in 37 C.F.R. 1.821(a)(1) and 1.821(a)(2). Accordingly, sequence identifiers have been incorporated by amendment into the Brief Description of the Drawings for Figures 8 and 9. Additionally, a description for Figure 11, including sequence identifiers, has been incorporated by amendment into the Brief Description of the Drawings. Reconsideration is respectfully requested.

Claims Rejections – 35 U.S.C. § 101

Claims 4, 8-10, 19, and 62-63 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility due to its not being supported by a specific,

substantial, and credible utility, or in the alternative, a well-established utility. The Examiner also made a related rejection under 35 U.S.C. 112, first paragraph, on the basis that since the claimed invention allegedly lacks a patentable utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully submit that the skilled artisan would recognize and appreciate that the Applicants' claimed sequence, based upon its identified prostate-specific expression profiles, indeed possesses utility under 35 U.S.C. § 101 in the context of the claimed invention.

The specification describes that the claimed polynucleotide was more highly expressed in prostate tumors, BPH and normal prostate than in normal non-prostate tissues, and, furthermore, that expression in normal prostate tissue was negative to low (*e.g.*, page 80, lines 1-15 of clean copy of enclosed substitute specification). Thus, the claimed sequence is described as having differential expression in prostate tumors relative to normal prostate tissue as well as non-prostate tissues. Applicants submit that the skilled artisan, in view of this disclosure, would have no difficulty understanding that the claimed sequence can be used as a diagnostic marker for the detection of prostate cancer tissue. For example, if a sequence is over-expressed in prostate tumor tissue relative to normal prostate tissue, then the detection of increased levels of the sequence in a prostate tissue sample suspected of being cancerous, relative to normal prostate tissue, would be indicative of the presence of prostate tumor tissue.

Furthermore, even if the sequence was expressed at similar levels in prostate tumors relative to normal prostate tissue (*e.g.*, was more tissue-specific than tumor-specific), the sequence would nevertheless still be in possession of diagnostic utility. Applicants note in this regard that it is not necessary for a sequence to be prostate tumor-specific (differentially overexpressed in prostate tumors relative to normal prostate tissue), in order for it to be useful diagnostically. Although differential overexpression of a sequence in tumor tissue versus normal tissue of the same tissue type is certainly one basis upon which a sequence can have diagnostic utility, the skilled artisan would appreciate that this is by no means the only basis. For example, a prostate-specific sequence can be used in the detection of metastatic prostate cancer cells that

have escaped the site of a primary prostate tumor. In this diagnostic scenario, expression of the sequence in normal prostate tissue is inconsequential.

Finally, Applicants note that it is not required to provide evidence sufficient to establish that an asserted utility is true “beyond a reasonable doubt.” *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965; emphasis added); *See also* MPEP 2107.02. Moreover, an applicant need not provide evidence that establishes an asserted utility “as a matter of statistical certainty.” Rather, a rigorous correlation is not necessary when a test is reasonably predictive of a result. *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980; emphasis added). Further still, in order to overcome the presumption of truth that an assertion of utility by the Applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, “question”) the truth of the statement of utility.” (*e.g.*, MPEP 2107.02 IIIA; emphasis added).

When viewed in this light, Applicants submit that the claimed invention is adequately supported by a patentable diagnostic utility, and would be recognized as such by an artisan of ordinary skill in view of the instant disclosure. Reconsideration of this rejection under 35 U.S.C. 101, as well as the related rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

Claims Rejections – 35 U.S.C. § 112

Claims 4, 8-10, 19, and 62-63 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. According to the Examiner, the claimed genus, due to the use of the open language “comprising”, encompasses species yet to be discovered, *e.g.*, full length cDNA constructs, etc., the specification does not provide an adequate description of the claimed genus.

As set forth above, and without prejudice to further prosecution or acquiescence to the stated ground for rejection, claim 4 has been amended to be drawn to an isolated polynucleotide consisting of a sequence set forth in SEQ ID NO: 313. The claimed invention is thus directed to a particular DNA sequence experimentally identified in the specification as

originally filed and acknowledged by the Examiner as being in Applicants' possession. Applicants request reconsideration of this rejection.

Claims 19 and 62 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth above, claim 19 has been canceled, without prejudice or acquiescence. As for claim 62, for reasons discussed above, it would be well recognized by the skilled artisan that the claimed sequence can be used, for example, as a diagnostic marker for prostate cancer tissue. Accordingly, Applicants submit that a skilled artisan could indeed make and use a diagnostic kit as claimed, and could do so without undue experimentation and with a reasonable expectation of success. Reconsideration is respectfully requested.

Claims Rejections – 35 U.S.C. § 102

Claim 8 stands rejected as allegedly being anticipated under 35 U.S.C. § 102 over NCI-CGAP (Database sequence, GenBank Accession No. AA578773, 9/12/1997) and over Bussemakers MJG (WO 98/45420-A1, 10/15/1998). According to the Examiner, the cited sequences are sequences that are partially complementary to the currently claimed sequence, and as a result, anticipate claim 8, absent an explicit definition for the term complementary.

Applicants respectfully traverse. For purposes of clarity and without acquiescing to the stated grounds for rejection, claim 8 has been amended to specify that the claimed complements are "completely complementary" to a polynucleotide according to claim 4. As the cited sequences are not completely complementary to the polynucleotide according to claim 4, the cited sequences fail to anticipate the currently claimed invention. Reconsideration is respectfully requested.

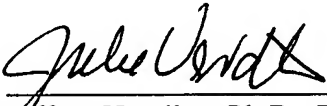
Application No. 10/010,940
Reply to Office Action dated September 24, 2004

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration is respectfully requested.

Respectfully submitted,

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Enclosures:

Postcard
Supplemental ADS
Substitute Specification with Changes Noted
Clean Copy of the Substitute Specification

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